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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,839	09/10/2001	Roland Heinze	P01,0235	8951

26574 7590 11/17/2003

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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 11/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,839

Applicant(s)

HEINZE ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/10/01 (Initial Filing & P. Amend.).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 September 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 14-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Based on the Applicant use of "average interval / duration" in the substitute specification, it appear the Applicant reads "average interval / duration" and "median interval/ duration" as synonymous limitations. An average value and a median value are different. The original specification uses the limitation "median interval/ duration". The Examiner is unable to find the limitation of an "average interval/ duration" in the original specification. New matter may not be added at this point in the prosecution. The limitation "average" in the claims should be changed to --median—at the following locations (claim/ line): 14/ 4, 10, 18, 23, 27; 18/ 2; 25/ 2 and 28/ 2, 3, 5).

3. Claims 14-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which

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it is most nearly connected, to make and/or use the invention. The Examiner is unable to find the limitation of an "average interval/ duration" in the original specification hence it is unclear how the "average interval/ duration" related to the systems and processes of the invention. It appears the limitation "average" in the claims should be changed to --median-- at the following locations (claim/ line): 14/ 4, 10, 18, 23, 27; 18/ 2; 25/ 2 and 28/ 2, 3, 5).

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-28 are unclear because the Examiner is unable to find the limitation of an "average interval/ duration" in the original specification hence it is unclear how the "average interval/ duration" related to the systems and processes of the invention. It appears the limitation "average" in the claims needs to be changed to --median-- at the following locations (claim/ line): 14/ 4, 10, 18, 23, 27; 18/ 2; 25/ 2 and 28/ 2, 3, 5).

In claim 25, "said control unit" lacks antecedent basis.

In claim 28, line 2, "said modulation unit" lacks antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-21, 23, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Heinze (US 5500006). Heinze discloses a pacemaker for acquiring a measurement parameter of heart activity, and evaluating the signal as a function of frequency or duration to optimize the pacemaker stimulation frequency (abstract; col. 2 @ 4-16; col. 2 @ 31- col. 3 @ 2; col. 3 @ 35-53; col. 5 @ 60 –col. 8 @ 31; col. 10 @ 19-39).

As to 15 and 16, the operation is continuous or periodic (col. 2 @ 7-10).

As to 17 and 20, the dimensionless variable, the actual duration of the action potential of the heart is used to identify the electric restitution (col. 3 @ 35-53).

As to claims 21 and 23, a quotient is used (col. 2 @ 44-40; col. 10 @ 33-37).

It is noted, as to the 35 U.S.C. 112 rejection related to the use of an average duration value or a median duration value, it is accepted that groupings of cardiac data can be evaluated based on the median value or the average value, the selection of the average value or median value being an obvious design choice.

Drawings

6. Figure 4 is objected to under 37 CFR 1.83(a) because the rectangular boxes/ symbols 1-5, 8 and 9 are not labelled as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Correction is required.

Specification

7. The substitute specification submitted 9/10/01 has been entered into the record.

8. The substitute specification filed 9/10/01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: “average duration”/ “average stimulation interval duration”/ “average adjusted interval duration”/ “average value”. It appears, based on the original specification, “average” should be replaced with --median—in the substitute specification. The reference to “average” is found in the substitute specification at (page/line): 4/21; 5/2, 7, 12, 13, 15; 6/4; 10/19 and 14/18. Applicant is required to cancel the new matter in the reply to this Office Action.

9. The disclosure is objected to because of the following informalities:

- Page 4, line 19, the phrase “stimulation pulses respectively separated by” is repeated twice,
- Page 6, line 14, “the20inequations” is unclear,
- Page 8, line 5, “5 AP” is unclear,
- Page 8, line 19, “as 25 a function” is unclear,
- Page 9, line 22, “pacemaker 25 it” is unclear,
- Page 10, line 3, “30” is unclear as no such reference numeral is found in the figures,
- Page 11, line 17, “the 10 regulation” is unclear,
- Page 13, line 3, it appears “too” should be --to--,
- Page 14, line 10, “telemetry 25 stage” is unclear,
- Page 14, line 19, “comparator 13” is unclear as no such reference numeral is found in the figures,
- Page 14, line 20, “follows. 5 The” is unclear, and
- Page 15, line 15, “Comparator 13” is unclear as no such reference numeral is found in the figures.

Appropriate correction is required.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist at telephone number (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
11/6/03

Angela D. Sykes

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